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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PALABRICA, RICARDO J

ART UNIT

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3663

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,975	Applicant(s) JONGEN ET AL.	
	Examiner Rick Palabrica	Art Unit 3663	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-14, 21-25, 27, 28 and 30-37 is/are pending in the application.
- 4a) Of the above claim(s) 8, 9, 13, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-12, 14, 21-25 and 30-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's 2/11/09 Amendment, which directly amended claims 1-4, 10, 23-25, canceled claim 7, 15-20, 26 and 29, added new claims 32-37 and traversed the rejection of claims in the 8/11/08 Office action, is acknowledged.

Applicant's arguments have been fully considered but they are not persuasive.

Response to Arguments

2. Applicant traversed the rejection of claims based on the applied art on the grounds that "[n]one of the cited references teach or suggest configuring the inlet and outlet so as to provide an essentially turbulent vortex in the flow of the target fluid inside the cavity."

The examiner disagrees.

In an attempt to define over the applied art in the 8/11/08 Office action, applicant, for example, has amended claim 1 to read as follows:

"an irradiation cell comprising a metallic insert which includes a cavity which receives the target fluid and an inlet and outlet which permits inflow and outflow of the target material, wherein the inlet and outlet provide an essentially turbulent vortex flow of the target fluid inside the cavity." Underlining provided

The claims are directed to an apparatus and NOT to a process. The structural limitations of an apparatus claim are the physical elements that are present in the apparatus when it is taken off the shelf or at the time of its removal from the shipping or storage container. In the instant case, the structural elements in the limitation of the

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amended claim are the following five elements: irradiation cell, metallic insert, cavity, inlet, and outlet.

The “target fluid” cannot be defined (or redefined) as a structure without destroying the ordinary (i.e., dictionary) meaning of the word, “structure.”

The underlined phrases in the above limitation are not structural elements of the claimed apparatus. Instead, they are statements of intended or desired use, or process limitations that are transitory, i.e., they occur only when the apparatus is exercised or made operational. As stated in the 8/11/08 Office action, process limitations, as well as statements of intended use do not serve to patentably distinguish the claimed structure over that of the reference, as long as the structure of the cited references is capable of performing the intended use. See MPEP 2111-2115.

See also MPEP 2114 that states:

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647.

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531.

[A]pparatus claims cover what a device is, not what a device does.” Hewlett-Packard Co. v. Bausch & Lomb Inc., 15 USPQ2d 1525, 1528.

As set forth in MPEP 2115, a recitation in a claim to the material or article worked upon does not serve to limit an apparatus claim.

Any one of the systems in the cited references is capable of being used in the same manner and for the intended or desired use as the claimed invention. Note that it is sufficient to show that said capability exists, which is the case for the cited references.

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3. As to applied art, Kiselev et al., Stanton, Wieland et al. and Shaeffer, applicant argues that neither one “teach or suggest that an inlet and an outlet are configured and arranged to provide an essentially turbulent vortex in the cavity.” Underlining provided.

The examiner disagrees,

First, either one of Kiselev et al. or Stanton or Wieland or Shaeffer disclose(s) the structural elements of an inlet and an outlet.

Second, the limitation, “configured to” or “arranged to” or “adapted to” perform a function does not constitute a limitation in any patentable sense, i.e., it only requires the capability to perform (e.g., see *In re Hutchison*, 69 USPQ 138 69 USPQ 138, or *National Presto Indus. V. West Bend Co.*, 76 F.3d 1185 (Fed. Cir. 1996)). Any one of Kiselev et al. or Stanton or Wieland et al. or Shaeffer, enables or permits the function recited in the claims to take place, and therefore either reference meets the claim limitations.

Third, applicant has not defined the degree or magnitude of turbulence associated with the so-called essentially turbulent vortex, and absent such definition the examiner interprets the term broadly and reads it on any and all forms and magnitude of flow vortex. Any one of one of Kiselev et al. or Stanton or Wieland et al. or Shaeffer is capable of providing a certain degree of turbulent vortex in some portion of the cavity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of Kiselev et al. (U.S. 6,567,492) or Stanton (U.S. 3,349,001) or Morelle et al. (IDS) or Scheffer et al. (ORNL/MIT-258) or Salsig, Jr. et al. (U.S. 2,868,987), or under 35 U.S.C. 102(a) as being anticipated by Wieland et al. (U.S. 7,200,198).

As to Kiselev et al. or Stanton or Wieland et al., the reasons are the same as those stated in section 4 of the 8/11/08 Office action, as further clarified in sections 2 and 3 above, which reasons are herein incorporated.

Morelle et al. disclose a device for producing fluorine-18 (see Fig. 1) having an irradiation cell with a metallic insert (i.e., nickel body) and a cavity, and inlet and outlet, a pump, an external heat exchanger. As to the pressurizing device, this reads the irradiator that provides energy to heat the target fluid, generate gases in the target chamber and raise the pressure in said chamber. Morelle et al. meet the process limitations in claims 2-6, 21 and 22 in the same manner as Kiselev et al. or Stanton or Wieland et al., as discussed in sections 2 and 3 above.

Shaeffer et al. disclose a device for F-18 production having an irradiation cell with a metallic insert, i.e., an inner cylinder of titanium (see Fig. 1 and page 11). Fig. 3 shows inlet and outlet, heat exchangers, a pump and pressurizing device (either the N₂ cylinder or the inherent heating of the target fluid that raises the system pressure). Shaeffer et al. meet the process limitations in claims 2-6, 21 and 22 in the same manner as Kiselev et al. or Stanton or Wieland et al., as discussed in sections 2 and 3 above.

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Salsig, Jr. et al. disclose a device for producing radioisotopes by bombarding a liquid target with a beam of high energy atomic particles. They disclose an irradiation cell 11 with a metallic insert 62 (see Fig 2), inlet 33, 38 and outlet 36 (see Fig. 2), heat exchanger 55 (see Fig. 3 and col. 4, lines 40+), pump 14 (see Fig. 2 and col.9, lines 26+) and pressurizing device, i.e., helium gas (see col. 9, lines 2+). Salsig, Jr. et al. meet the process limitations in claims 2-6, 21 and 22 in the same manner as Kiselev et al. or Stanton or Wieland et al., as discussed in sections 2 and 3 above.

5. Claim 32 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of Kiselev et al. or Scheffer et al., or under 35 U.S.C. 102(a) as being anticipated by Wieland et al.

Any one of the above applied art has a cavity volume of at least 5 ml. (e.g., see col. 4, lines 60+ in Kiselev, or claim 4 in Wieland et al., or Table 5 in Schaeffer et al.

6. Claims 10-12, 14, 23-25, 30 and 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Salsig, Jr. et al.

As to claim 10, see, e.g., Fig.3 showing the head-on collision between the particle beam and the target fluid. Applicant's claim language, "irradiation window" reads on the junction between the inlet 33 and the cyclotron 12.

As to claims 11 and 30, see, e.g., Fig. 3 showing the inlet 38 being along the central axis of cavity 11 and outlet 36 being connected to a lateral surface of the cavity.

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As to claims 12 and 14, cooling means 55 is disposed internal to the cavity and provides indirect cooling of said cavity (see Fig. 2).

As to claims 23, 24, 25 and 33-37, applicant's claim language, "external heat exchanger" reads on cooling coils 83 (see Fig. 2 and col. 6, lines 54+). As to the limitation in the claims "configured to ..." (i.e., in claims 23-25 and 33-37), Salsig Jr. et al. is capable of meeting these limitations (see also section 3 above).

As to claim 31, applicant's claim language, "internal cooling" reads on cooling means 55 located within cavity 11 (see Fig. 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2-6 and 22 are rejected under 35 U.S.C. 103(a) as being obvious over one of Kiselev et al. or Stanton or Wieland et al. ('198) or Morelle et al. or Scheffer et al. or Salsig, Jr. et al.

In section 4 above, the examiner demonstrated that these process claims are met by the cited applied art because each one is capable of being used in the same manner and for the intended or desired use as the claimed invention. If applicant is of a different opinion, these claims are still unpatentable because they are obvious over said applied art.

The pump flow rate and the maximum temperature of the target fluid, as recited in claims 2-4, and the volume of the target fluid, as recited in claims 5 and 6, are matters that depend upon the design constraints imposed on the apparatus. Also the specific values for the parameters are subject to optimization, which includes the balancing of factors such as cost vs. operational performance, etc. As to matters of optimization within prior art conditions or through routine experimentation, see MPEP 2144.05 II.A.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rick Palabrica whose telephone number is 571-272-6880. The examiner can normally be reached on 6:00-4:30, Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jack Keith can be reached on 571-272-6878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rick Palabrica/
Primary Examiner, Art Unit 3663

March 30, 2009